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IN THE

Supreme Court of the United States

October Term, 1976
No. 76-513

INTERNATIONAL RECTIFIER CORPORATION, *et al.*,
Petitioners,

vs.

PFIZER INC.,
Respondent.

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI.

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INTERNATIONAL RECTIFIER CORPORATION, *et al.*,
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PFIZER INC.,
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BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI.

I
QUESTION PRESENTED.

Respondent Pfizer Inc. (Pfizer) submits that the question presented for review by petitioners seeks an advisory opinion of this Supreme Court, since the Eighth Circuit decision did not turn on resolution of subjective intent. Therefore, pursuant to Rule 40(3) of this Supreme Court, Pfizer restates the question as follows:

(1) Was reversal of the summary judgment invalidating the patent for fraud or inequitable conduct in the Patent Office proper, where there are genuine issues of material fact including: (a) whether information was withheld from the Patent Office; (b) if so, whether such information was material to issuance of the patent; and (c) if so, whether the information was intentionally withheld; and

(2) Is it not premature to render an opinion as to whether subjective intent to commit fraud is an element of proof, when that issue may never be reached on remand?

II
STATEMENT OF THE CASE.

The statement of the case submitted by petitioners International Rectifier Corporation, *et al.* (Rectifier) is inaccurate, and the following statement is provided in accordance with Rule 40(3) of this Supreme Court.

Pfizer is the owner of U.S. Patent No. 3,200,149 disclosing and claiming, *inter alia,* a broad spectrum antibiotic, doxycycline (α-6-deoxy-5-oxytetracycline). Doxycycline was invented in Pfizer's laboratories after years of costly research, and it has proved to be one of the most effective and successful antibiotics in mankind's continuing struggle against disease. The doxycycline patent issued in 1965 and was not infringed until Rectifier commenced infringement in January 1973. Rectifier's infringement is willful and flagrant.

The Course of the Proceedings.

Pfizer filed its complaint for patent infringement on January 10, 1973. Rectifier's answer admitted infringement and pleaded the usual defenses of invalidity and unenforceability, including the assertion that the patent would not have issued but for fraud on the Patent Office.

Rectifier moved for summary judgment before the Honorable Miles Lord of the District of Minnesota, based upon its "explanation" of documents, each explanation being a contention that the court should draw some improbable inference adverse to Pfizer (and

contrary to other evidence) rather than an obvious, reasonable inference in Pfizer's favor. The motion included but one affidavit.

Pfizer opposed the motion factually with 54 exhibits and 24 affidavits which set forth specific facts showing genuine issues for trial (Rule 56(e), F.R.Civ.P.).

Disposition in the District Court.

Rectifier's motion, described by the district court during the hearings as involving "very complicated allegations," was granted by partial summary judgment of patent invalidity and unenforceability on July 16, 1975 after eleven days of hearings and argument stretched over the period from September 1974 through April 1975.

In deciding a motion which presupposes that no issue of material fact exists, Judge Lord based his summary judgment on 150 numbered findings of fact plus 64 conclusions of law that were "intended to include" additional findings of fact—findings that encompassed 80 pages. Each supposedly uncontroverted fact found by the district court and essential as a basis for its summary judgment was contradicted by the record. Likewise, many "Conclusions of Law" were actually findings on hotly disputed issues of fact which must be resolved by trial.

The Eighth Circuit reversed the partial summary judgment because Judge Lord had resolved genuine issues of material fact, contrary to the mandate of Rule 56, F.R.Civ.P. (A. 112, 115, 116, 118, 120).* The Court of Appeals also noted that the district

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*The appendix to the Petition is referred to herein as A and Pfizer's appendix included herein is referred to as PA.

court had improperly resolved "matters of intent; good faith and credibility" in the summary proceeding, (A. 102), and remanded the case for trial, stating that the "scientific issues at stake are of such moment that all parties should be permitted to present their evidence fully in a plenary trial not restricted to a trial by affidavit." (A. 100).

III
ARGUMENT.

Summary of the Argument.

The Petition presents no special or important question.

1. The Eighth Circuit reversed the summary judgment on the ground that numerous genuine issues of material fact exist with respect to the charges of fraud and inequitable conduct, correctly applying the standards governing summary judgment established by this Court. *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 467 (1962); *Adikes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970).

2. There is no conflict between the circuits as to any point of law relied on by the Eighth Circuit. The Court of Appeals correctly set forth the law governing fraud and inequitable conduct as established by this Supreme Court and applied by the circuit courts.

3. The opinion of the Eighth Circuit is interlocutory in nature, and hence is not properly reviewable by this Supreme Court, since it amounts to a denial of a motion for summary judgment on the grounds that there are genuine issues of material fact. Since critical and complex factual issues remain to be resolved by trial, petitioners are asking this Supreme Court to render an opinion that will be advisory at best. If Pfizer's

position, that no material facts were withheld or misrepresented, is accepted by the trier of facts on remand, this Supreme Court's opinion would be merely academic since the issue of subjective intent to commit fraud will not even be reached. This Supreme Court has consistently refused to give advisory opinions. *United States v. Fruehauf*, 365 U.S. 146, 157 (1961); *Flast v. Cohen*, 392 U.S. 83, 95-96 (1968).

Argument.

1. There Are Genuine Issues of Fact as to Whether Pfizer Withheld or Misrepresented Any Material Facts and Whether It Acted Deliberately.

Rectifier would have this Supreme Court believe that the facts which underlie its charge of fraud on the Patent Office are not contested and that the Eighth Circuit based its decision entirely on Rectifier's failure to prove that the alleged fraud was perpetrated with a specific intent or evil motive (Pet. 5).* On the contrary, the basis of the reversal was the existence of genuine issues of material fact with respect to each element of the alleged fraud. In its decision, the Court of Appeals properly applied the law of fraud on the Patent Office as established by this Supreme Court and the Circuit Courts of Appeal (A. 105-06).**

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*The Petition is referred to herein as Pet.

***Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814-15 (1945); *Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 598, 601 n.14 (3d Cir.), *cert denied*, 407 U.S. 934 (1972); *Schnadig Corp. v. Gaines Manufacturing Co.*, 494 F.2d 383, 393 (6th Cir. 1974); *Kolene Corp. v. Motor City Metal Treating, Inc.*, 440 F.2d 77, 83 (6th Cir.), *cert. denied*, 404 U.S. 886 (1971); *Scott Paper Co. v. Fort Howard Paper Co.*, 432 F.2d 1198, 1204-05 (7th Cir. 1970), *cert. denied*, 401

(This footnote is continued on next page)

The Eighth Circuit held that each element of fraud or inequitable conduct "must be established by 'clear, unequivocal and convincing' evidence. *United States v. American Bell Telephone Co.*, 167 U.S. 224, 251 (1897). . . ." (A. 106).

Rectifier contends that no genuine issues of fact exist and represents that it is undisputed that certain facts were withheld from the Patent Office, that they were "material" to the issuance of the patent, and that Pfizer deliberately withheld them (Pet. 8). Pfizer refuted these contentions (which were principally based on argument of counsel or strained inference sought to be drawn from voluminous documents) with detailed affidavits, including two from Patent Examiner Adams who examined and allowed the doxycycline application, seven from Pfizer's scientists, one from a Nobel Laureate in chemistry and former Pfizer scientific consultant, one from a former Patent Office Examiner-in-Chief who authored the initial draft of what is now the Patent Act of 1952, and two from the patent attorney who prosecuted the application.

Rectifier has inaccurately characterized those affidavits as merely asserting, "I didn't mean it." (Pet. 8).

U.S. 913 (1971); *Parker v. Motorola, Inc.*, 524 F.2d 518, 535 (5th Cir. 1975); *Norton v. Curtiss*, 433 F.2d 779, 793-95 (C.C.P.A. 1970); *Acme Precision Products, Inc. v. American Alloys Corp.*, 484 F.2d 1237, 1239-40 (8th Cir. 1973); *Cataphote Corp. v. DeSoto Chemical Coatings, Inc.*, 450 F.2d 769, 772 (9th Cir. 1971), *cert. denied*, 408 U.S. 929 (1972); *Nashua Corp. v. RCA Corp.*, 431 F.2d 220, 227 (1st Cir. 1970); *Triumph Hosiery Mills, Inc. v. Alamance Industries, Inc.*, 299 F.2d 793, 796 (4th Cir.), *cert. denied*, 370 U.S. 924 (1962); *Edward Valves, Inc. v. Cameron Iron Works, Inc.*, 286 F.2d 933, 947, *modified on other grounds*, 289 F.2d 355 (5th Cir.), *cert. denied*, 368 U.S. 833 (1961); *Carter-Wallace, Inc. v. Davis-Edwards Pharmacal Corp.*, 443 F.2d 867, 882 (2d Cir. 1971); *Haloro, Inc. v. Owens-Corning Fiberglas Corp.*, 266 F.2d 918 (D.C. Cir. 1959).

Pfizer has reproduced in the appendix hereto the affidavit of the attorney who prosecuted the application and an affidavit furnished by the Patent Examiner.* (PA). Those affidavits are exemplary of the detailed factual evidence lodged in opposition to the summary judgment motion, but ignored by the district court.

In view of this evidence, the Eighth Circuit properly held that the district court had erroneously resolved questions of fact with respect to each issue, and reversed, holding:

> We think the court erred in granting partial summary judgment, as genuine issues of material fact exist with respect to each of Pfizer's five alleged acts of misconduct before the Patent Office. . . . (A. 100).

Additional Issues of Technical Fact.

Rectifier concedes that the Eighth Circuit based its reversal of the summary judgment on the existence of issues of technical fact which are unsuited for summary resolution. (Pet. 5). However, it asserts that the district court's misconception of the technical subject matter was not an issue on appeal and that therefore this Supreme Court should ignore the existence of these fact questions, despite the Eighth Circuit's holding that expert testimony is required to resolve them.

It is incredible for Rectifier to represent that the confusion of the district court with respect to technical fact issues was not an issue on appeal. Pfizer argued

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*Rectifier has inaccurately characterized the Examiner's affidavit as containing "inapplicable hypotheticals." (Pet. 18). In fact, the sole affidavit relied upon by Rectifier was based on hypotheticals and it was so characterized by the Examiner himself (PA 1-2).

to the Eighth Circuit that the summary judgment was improper because of the need for expert testimony, as demonstrated by the district court's total failure to comprehend the technical subject matter. For example, Pfizer argued: "The consequence of dispensing with expert testimony and trial is demonstrated by the existence of basic factual errors and misunderstandings from beginning to end in the Findings and Conclusions." (Pfizer's Opening Bf. to the 8th Cir. p. 17). And the Court of Appeals opinion stated, "On this appeal, Pfizer challenges the District Court's rulings as violative of the cardinal principle that summary judgment is permitted only if there is 'no genuine issue as to any material fact,' Fed. R. Civ. P. 56(c). . . ." (A. 99).

Rectifier has selected the ruthenium issue as illustrative of its position. It argues that the Examiner would have rejected at least the principal process claim had he known of alleged experimental failures, and represents that all of Pfizer's efforts to use ruthenium in the patented process prior to issuance of the patent were unsuccessful (Pet. 14).

Each of Rectifier's premises is false. Rectifier chooses to ignore the affidavit of the Examiner which directly contradicts its first premise (PA 8-9), and also ignores records of experiments conducted prior to the filing date of the application which contradict its second premise. Such records demonstrate the successful use of ruthenium to produce doxycycline. With respect to one experiment (A. 134), Rectifier argues the inferences to be drawn from the phrase "little hydrogenation." It offers no evidence supporting its interpretation but invites this Supreme Court (as it invited the courts below) to draw an unreasonable inference, adverse to the party opposing the motion for summary judgment—

contrary to all precedent. The Eighth Circuit properly rejected the invitation. "Our review of the record reveals unresolved technical issues concerning Pfizer's success with the chemical processes and genuine issues of material fact as to Pfizer's willfulness in allegedly concealing lack of success." (A. 120).

Rectifier has succeeded only in exemplifying the strained inferences which it has sought to draw from technical documents unaided by expert testimony and the factual issues which remain to be litigated.

The Eighth Circuit recognized the existence of unresolved technical fact issues which required reversal: "additional issues of technical fact are present that are unsuited for summary resolution without the benefit of live expert testimony" (A. 112); "we believe genuine issues of material fact are present, concerning . . . the examiner's understanding of technical facts" (A. 115); "we believe the issues of fact joined by these contrasting contentions are genuine and material" (A. 116); "Our review of the record reveals unresolved technical issues concerning Pfizer's success with the chemical processes. . . ." (A. 120).

Since genuine issues of material fact exist with respect to each element of the alleged fraud, reversal of the summary judgment was proper and there is no question which merits review by this Court.

2. There Is No Conflict Between the Circuits.

Rectifier attempts to create a conflict between the circuits by arguing that the Eighth Circuit has required proof of willfulness, in addition to materiality, in order to prove fraud on the Patent Office, whereas it asserts that the Third and Ninth Circuits do not require proof of willfulness. (Pet. 11). No such conflict exists.

In fact, the Eighth Circuit applied the standard of proof established by this Supreme Court and utilized by the various Circuit Courts of Appeal, including the Third and Ninth Circuits. The Eighth Circuit held that in order to bar enforcement of a patent there must be "some element of wrongfulness, willfulness, or bad faith." (A. 105). The opinion of the Eighth Circuit catalogues the cases of the other circuits, all of which are in accord. The Eighth Circuit distinguished the cases upon which Rectifier relied below (and on which it places its reliance in this Supreme Court) as not supporting the proposition for which Rectifier cites them:

> Defendants' [Rectifier's] contention that willfulness or a similar state of mind need not be proved to render misconduct sufficiently inequitable to vitiate a patent is not supported by *Monsanto Co. v. Rohm & Haas Co.*, [456 F.2d 592, 598, 601 n.14 (3rd Cir.), *cert. denied*, 407 U.S. 934 (1972)]; *Beckman Instruments, Inc. v. Chemtronics, Inc.*, 428 F.2d 555, . . . (5th Cir.) *cert. denied*, 400 U.S. 956 (1970); and *Monolith Portland Midwest Co. v. Kaiser Aluminum & Chemical Corp.*, 407 F.2d 288 (9th Cir. 1969) upon which they rely. In *Monsanto*, the court found that knowingly false statements were made to the Patent Office and material facts deliberately concealed that would otherwise have resulted in denial of the Patent. 456 F.2d at 595, 601 n.14. Similarly, in *Beckman Instruments*, the court found that knowledge of the prior art was deliberately withheld and would have resulted in denial of the patent. 428 F.2d at 560, 564-65. And in *Monolith Portland*, a deliberate withholding

> of crucial information that would also have resulted in denial of the patent was recognized to justify an award of attorneys fees under the "exceptional cases" rule of 35 U.S.C. § 285. 407 F.2d at 294-97. (A. 106 n.14.)

Rectifier now also relies on *Robbins Co. v. Lawrence Mfg. Co.*, 482 F.2d 426 (9th Cir. 1973). (Pet. 12). However, *Robbins* did not involve the question of intent in connection with a charge of fraud or inequitable conduct before the Patent Office. The case is simply not in point. The sole question before the court in *Robbins* was whether the prior sale of the patented device was an invalidating sale or an experimental use. In view of the uncontroverted facts of the sale of the device for in excess of $400,000, its extensive use, and lack of any follow-up by the inventor, the court rejected the "conclusory" affidavits of the inventor and his friend claiming that the use of the device eight years earlier was experimental.

Summary judgments invalidating patents for fraud on the Patent Office are rare and Rectifier can cite only two district court cases on which to rely. (Pet. 8). The cases are inapposite. In *Farmer Bros. Co. v. Coca Cola Co.*, 384 F.Supp. 595 (C.D. Cal. 1974), the patentee *admitted* that prior to filing the application he knew of a prior public use which was a statutory bar to patentability, and summary judgment was entered based on that admission. The district court in *Interlego, A.G. v. F.A.O. Schwarz, Inc.*, 187 U.S.P.Q. 580 (N.D. Ga. 1975) has reconsidered its opinion and order granting summary judgment and has entered an order denying summary judgment because of the existence of genuine issues of material fact. (191 U.S.P.Q. 129 (N.D. Ga. 1976)).

3. Rectifier's Standard of Disclosure Would Be Unworkable, Has Not Been Adopted by Any Circuit and Was Properly Rejected by the Court of Appeals.

Rectifier first creates an unworkable standard of disclosure to the Patent Office and then designates noncompliance with that standard as fraud. It argues that "all facts which may be relevant to an issue of patentability" must be submitted to the Patent Office, using "relevant" in the sense of anything and everything related to the subject. (Pet. 12). All such information is said to be "material." (Pet. 12-14).

Thus Rectifier argues that a patent applicant may not exercise good faith judgment in determining what information is of sufficient relevance or materiality to require submission; he must submit everything. Relying on this proposed standard of disclosure, Rectifier proceeds to argue that if all such information is not submitted, it is "deliberately" withheld. It uses "deliberate" in the sense of "intending to do an act" as opposed to "intending to do an act with the accompanying motive of also intending to commit a fraud. . . ." (Pet. 5). Thus, any decision not to submit a given item under Rectifier's broad definition of relevant would become a "deliberate" withholding of "material" facts and thus—by Rectifier's definition—fraud.

Relying on this bizarre definition of terms, Rectifier concludes that "the Uncontroverted Facts Are That the Patentee Deliberately Withheld Material Facts . . ." and argues that summary judgment is proper where the "uncontroverted facts demonstrated that the patentee procured its patent by fraudulent or inequitable conduct." (Pet. 8). Having *assumed* that fraud is uncontested, Rectifier then argues that it should not *in addition* have to prove Pfizer's subjective intent to commit fraud (Pet. 8).

What Rectifier has in effect done is to avoid facing the issue of "wrongfulness, willfulness, or bad faith" at any stage of the proceeding. Thus Rectifier urges that intent or good faith is totally irrelevant and need never be considered.

Rectifier urges a strict liability standard, where the exercise of good faith judgment is precluded and fraud automatically follows despite the failure to prove some element of bad faith. This standard calls for submission to the Patent Office of every piece of information in any way related to the general subject of the invention. Such a procedure would easily overwhelm the Patent Office and serve no useful purpose. The suggested standard is unrealistic and has never been applied by the Patent Office, the Courts of Appeal, or this Supreme Court.

The Eighth Circuit correctly recognized that Rectifier's standard is unworkable and that a patent applicant must exercise good faith judgment in determining the facts to be submitted to the Patent Office. (A. 104). The decision of the Eighth Circuit conforms to the standard of the other circuits, all of which require "some element of wrongfulness, willfulness, or bad faith" in order to render a patent invalid or unenforceable for fraud or inequitable conduct in the Patent

Office (A. 105-06, nn.13-14). Any lesser standard would be a dramatic departure from precedent and would expand "the inequitable conduct defense beyond legitimate limits." (A. 104).

The standard applied by the Eighth Circuit was well stated by the Second Circuit:

> We agree with the statement in *Xerox Corp. v. Dennison Mfg. Co.*, 322 F.Supp. 963 (S.D.N.Y. 1971), that in order for non-disclosure to constitute inequitable misconduct there must be something more than negligence—that *there must be "some element of wrongfulness, willfulness or bad faith* that transgresses the basic concept of doing equity." (Emphasis supplied). *Carter-Wallace, Inc. v. Davis-Edwards Pharmaceutical Corp.*, 443 F.2d 867, 881-82 (2d Cir. 1971), *cert. denied*, 412 U.S. 929 (1973).

The Patent Office has recently proposed rules of practice which express the same view with respect to the duty of a patent applicant.* The accompanying text states the Patent Office's intention to codify "existing Office policy on fraud and inequitable conduct, which is believed consistent with the prevailing case law in the Federal courts." (41 Fed. Reg. at 43730).

The proposed rules would require the disclosure of the most relevant prior art within two months after filing the application, with "relevant" being defined as "that which might reasonably be expected to affect the decision of the examiner." (41 Fed. Reg. at 43733). With respect to this requirement, the Commissioner states:

> It of course requires persons to exercise judgment in deciding what information to cite. No

*41 Fed. Reg. 43729 (Oct. 4, 1976).

> way has been found to avoid the exercise of judgment if the examiner is to be provided only with information useful to him. The intent of the Office is to avoid penalizing persons for good faith errors in judgment in deciding what information to bring forward. (41 Fed. Reg. at 43730.)

The standard of disclosure suggested by Rectifier was properly rejected by the Eighth Circuit as unworkable. Good faith is pertinent in determining a charge of fraud on the Patent Office, and the Eighth Circuit properly included it among the numerous other genuine issues of material fact present in this case which preclude summary judgment. There is no conflict between the circuits; each requires clear and convincing proof of some element of wrongfulness, willfulness, or bad faith.

4. The Decision of the Court of Appeals Is Interlocutory in Nature and Is Not Properly Reviewable by Certiorari.

The Court of Appeals decision which Rectifier asks this Supreme Court to review reverses a summary judgment because of unresolved issues of fact. As such, the appellate decision amounts to a denial of a motion for summary judgment, is interlocutory in nature, and is not suitable for review by this Supreme Court.

The Court of Appeals held: "We think the court erred in granting partial summary judgment, as genuine issues of material fact remain as to each of Pfizer's five alleged acts of misconduct before the Patent Office. . . ." (A. 100).

In view of this unequivocal statement by the Court of Appeals, which reviewed and analyzed the 5,000 page Joint Appendix, this Supreme Court should not

grant certiorari to again sift the evidence. "We do not grant a certiorari to review evidence and discuss specific facts." *United States v. Johnson,* 268 U.S. 220, 227 (1925).

This Supreme Court has long held that decisions of district courts denying motions for summary judgment are not final judgments and therefore that courts of appeal are without jurisdiction to review them on appeal. *United States v. Florian,* 312 U.S. 656 (1941). Since the decision of the Court of Appeals merely remands the case for trial because of the existence of genuine issues of material fact, it is not appropriate for review by certiorari.

> [D]enial of a motion for summary judgment because of unresolved issues of fact does not settle or even tentatively decide anything about the merits of the claim. It is strictly a pretrial order that decides only one thing—that the case should go to trial. *Switzerland Cheese Assoc., Inc. v. Horne's Market, Inc.,* 385 U.S. 23, 25 (1966).

Moreover, if on remand the trial court accepts Pfizer's contention that no material facts were withheld or misrepresented to the Patent Office, the issue of subjective intent to commit fraud will never be reached. The opinion sought from this Supreme Court by Rectifier is thus an advance expression of a legal judgment upon conjectural fact issues which may never need to be resolved by the trier of fact. This Supreme Court has consistently refused to render such advisory opinions. *United States v. Fruehauf,* 365 U.S. 146, 157 (1961); *Flast v. Cohen,* 392 U.S. 83, 95-96 (1968).

IV
CONCLUSION.

The Court of Appeals detailed the reasons requiring reversal of the summary judgment. The Court of Appeals had the benefit of the Joint Appendix including over 150 pages of affidavits. The Eighth Circuit opinion rests on the existence of genuine issues of material fact—the nemesis of any summary judgment.

Rectifier's statement that there are no issues of fact is not supported by the record and is directly contradicted by the opinion of the Court of Appeals. There is no conflict between the circuits with respect to any principle of law relied upon by the Eighth Circuit and there is nothing in their opinion which merits review by this Supreme Court. Since the factual issues remain to be determined at trial, it would be inappropriate for this Supreme Court to write an advisory opinion on issues which may never be reached by the trial court.

For all of these reasons, it is respectfully submitted that the petition should be denied.

Dated: December 3, 1976.

Respectfully submitted,

DEAN C. DUNLAVEY,
Attorney for Respondent Pfizer Inc.

APPENDIX

APPENDIX.

Adams—February 24, 1975.

Second Supplemental Affidavit of James Walter Adams, Jr.

I, James Walter Adams, Jr., being duly sworn, depose and say:

1. I am the same James Walter Adams, Jr. who executed an affidavit on October 9, 1974, and who also executed an affidavit on February 3, 1975, hereinafter referred to as my "Supplemental Affidavit."

2. On January 30, 1975, I met at a local Holiday Inn with Peter R. Cohen and Marc Gross at their request. I understand that Mr. Cohen and Mr. Gross are counsel for defendant International Rectifier Corp. in an action instituted by Pfizer Inc. for infringement of U.S. Patent No. 3,200,149 (Blackwood et al). At this meeting Mr. Cohen and Mr. Gross told me that there were documents and information known to them that they were not at liberty to disclose to me, and that they would therefore pose to me a series of hypothetical questions or propositions. They then did so and I discussed with them my speculations based thereon.

3. On February 3, 1975, Mr. Cohen and Mr. Gross submitted to me the aforementioned Supplemental Affidavit which included some of my comments, reactions and speculations in regard to hypothetical questions and circumstances which they had posed to me at our meeting on January 30, 1975.

4. More specifically, paragraphs 4, 5 and 7-10 of that Supplemental Affidavit, executed on February 3, 1975, contain or relate to my speculations based

upon hypothetical questions posed to me by Mr. Cohen and Mr. Gross. Indeed, the phrase "I would have been interested in and considered material", or words to that effect, which appear repeatedly in my Supplemental Affidavit were not suggested by me but rather were formulated by Mr. Cohen and Mr. Gross.

At the meeting with them on January 30, 1975, after several "hypotheticals" had been presented to me and I had acknowledged that I would have been interested in and considered material the hypothesized facts or circumstances, I stated that it was my belief that all examiners, including myself, would have been interested in and considered material, facts and circumstances of the type they were suggesting at the time the Blackwood, et al. application S.N. 106,146 was being prosecuted. However, I cautioned them that this did not indicate any belief on my part that applicants were under any duty to make known such facts and circumstances or that if made known, such facts and circumstances would necessarily reflect adversely on the ultimate question of patentability.

I am aware of no facts that would cause me to alter my decision to allow the claims of U.S. Patent No. 3,200,149 (Blackwood et al). Moreover, I advised Mr. Cohen and Mr. Gross that the statements contained in my Supplemental Affidavit should not be interpreted as indicating any belief on my part that the claims of U.S. Patent No. 3,200,149 were improperly allowed.

5. Paragraph 3 of my Supplemental Affidavit was not intended to imply that Belgian Patent No. 572,584 was cited to me by Mr. Oglesby in connection with another matter. As I stated in Paragraph 6 of my Affidavit of October 9, 1974, I do not now recall

the circumstances under which I first received or otherwise became aware of Belgian Patent 572,584. Whether Mr. Oglesby directed my attention to Belgian Patent 572,584 or whether I found that reference myself was not material to me and did not affect the patentability of the subject matter of the Blackwood et al application from my viewpoint. It should be noted that I based a rejection on Belgian Patent No. 572,584 during the course of prosecution of the Blackwood et al application before passing that application to issue. See Official Action of January 19, 1965 pages 94-95 of the file wrapper.

6. The first sentence of Paragraph 4 of my Supplemental Affidavit repeats the statements of fact set forth in Paragraph 7 of my October 9, 1974 Affidavit, i.e. that during prosecution of the Blackwood et al application, I was not interested in the absolute stereochemical configuration of either the known 6-deoxytetracyclines or the compounds claimed in the Blackwood et al application. The remainder of Paragraph 4 of my Supplemental Affidavit, concerning what I might have done prior to *In re Brown* (141 USPQ 245), is speculation based on hypothetical facts and circumstances posed to me by Mr. Cohen or Mr. Gross. When the hypothesis of this paragraph was suggested to me by Mr. Cohen or Mr. Gross, I advised them that I considered the decision of the Court of Customs and Patent Appeals in *In re LeGrice* (133 USPQ 365) to be applicable. The fact is that I was away from the Patent Office from on or about April 29, 1962 until on or about October 25, 1964. Thus, Mr. Oglesby would not have told me anything about the Belgium patent during that period. When I returned to the Patent Office in October 1964, *In re LeGrice*

and *In re Brown* represented the applicable case law for *von Bramer* rejections.

Moreover, I note from the file wrapper of the Blackwood et al application that, during my absence from the Patent Office, in the second Official Action dated October 30, 1962 (page 68 of the file wrapper) Examiner Berg did in fact reject the product claims under 35 U.S.C. 102 as anticipated by the Belgian patent. Thus, Examiner Berg made the very rejection hypothesized in Paragraph 4 of my Supplemental Affidavit.

Moreover, the fact is that it would not have been proper for me to make a final rejection under 35 U.S.C. 102 in view of the Belgian Patent due to *In re LeGrice* and *In re Brown*. However, as noted in Paragraph 5 above, I did make a rejection of certain claims in view of the Belgian Patent under 35 U.S.C. 103 and that was a final rejection, which was successfully overcome.

With respect to 5-position stereochemistry, I note that it is of record in the file wrapper, at pages 72, 75 and 79-80, that the orientation of the 5-hydroxyl group had yet to be definitively established. Thus, the amendment passage at page 72 of the file wrapper states:

> Prior to the *In re LeGrice* decision, applicants' claims did not cover 6-epi-6-deoxytetracycline and substituted derivatives thereof as now embraced by amended claim 9 and newly submitted claims 18-21. Thus, the *von Bramer* nature of the applied references appeared to be a full anticipation of these newly claimed compounds for the reason that the 5-position stereo chemistry thereof, involving only hydrogen substituents, did not offer

> room to argue that the three applied references failed as a full structural anticipation as appeared possible in the case of the corresponding 6-epi-6-deoxy-5-oxytetracyclines.

This tells me why the applicants regarded the applied references as failing as von Bramer anticipations of the 6-epi-6-deoxy-5-oxytetracyclines; that is, the orientation of the 5-hydroxyl group was believed to be different in the 6-epi-6-deoxy-5-oxytetracyclines from that depicted in the applied references.

The uncertainty of the stereochemistry at the 5-position in oxytetracyclines to others skilled in the art is further apparent to me from the 1962 publications contained in the file wrapper, including specifically the wavy line in Formula I at page 75 of the file wrapper and the passages at pp 79-80 of the file wrapper which are embraced by marginal brackets in the file wrapper copies.

With respect to applicants' obligations, I observe that the standard oath subscribed to by the inventors states *inter alia* that they do not know and do not believe that their invention was ever described in a printed publication before their invention or more than a year prior to the filing date. The Oath does not state, and it is my belief that it is not required by the Patent Law that it state, that the inventors know conclusively that their invention was never so described. During my tenure in the Patent Office I understood the law to merely require that applicants have a good faith belief that their invention is novel—that is, different from the prior art known to them. It was not my understanding that applicants were held to a standard of absolute assurance of novelty, and indeed such

heavy burden of certainty would utterly preclude the signing of an oath and thus the filing of any patent application on any invention.

Paragraph 4 of my Supplemental Affidavit was not intended (1) to imply that I could have issued a final rejection based on the speculation that the Belgian patent might some day be found to be a von Bramer anticipation, or (2) to imply that I would have required such speculation to be conclusively disproven.

Thus, Paragraph 4 of my Supplemental Affidavit, with the exception of the first sentence thereof, is nothing more than speculation as to what I might have done or would have done, in retrospect, had certain facts and circumstances been different from (1) what they actually were or (2) what they were believed by me to be.

7. In Paragraph 6 of my Supplemental Affidavit I inserted the term "reliable", which I intended as a synonym for "conclusive", in the draft presented to me by Mr. Gross and Mr. Cohen. By "reliable" and "conclusive" I intend to describe that level of scientific evidence, which quantitatively and qualitatively, would be regarded as convincing by a prudent, experienced chemist skilled in the art.

Paragraph 7 of my Supplemental Affidavit contains my speculations as to what I might have been interested in if the hypothetical issue had been raised, i.e. if I had rejected the product claims on the basis of prior art coproduction. It is clear from the file wrapper of the Blackwood et al application that in fact I did not reject the product claims on the basis of coproduction. Based upon the pages 106-107 of the file wrapper I was clearly aware that Pfizer had paper

chromatography evidence of possible coproduction but had not established that coproduction did indeed occur. However, the March 5, 1965 response filed by Mr. Oglesby, and particularly the statements at pages 106-107 of the file wrapper, were adequate to overcome a coproduction rejection although no such rejection was made.

With further reference to Paragraph 7 of my Supplemental Affidavit, and in particular the first sentence thereof, I find that the prior art cited in prosecution was not limited to the use of any specific reaction conditions such as a particular catalyst, but included references teaching the hydrogenolysis of tetracyclines in the presence of various noble metal catalysts under a variety of conditions.

Paragraphs 5-7 of my Supplemental Affidavit, and particularly the last sentence of Paragraph 7, imply that I lacked information with regard to coproduction. However, I note that in his amendment of March 5, 1965, in commenting on possible coproduction, Mr. Oglesby stated (file wrapper, p. 107):

> If the Examiner wishes further information in connection with the identity of the actual crude materials investigated, the procedures employed, etc., then, upon request which is made of record, the undersigned attorneys will arrange to produce the records thereof and allow the Examiner to discuss the same with the investigator and any other knowledgeable employee of the unrecorded assignee herein.

I did not avail myself of this offer as I considered the information provided concerning possible coproduction as sufficient to establish patentability had copro-

duction, in fact, been an issue with respect to patentability.

8. The statements made in Paragraph 8 of my Supplemental Affidavit are based on the hypothetical assumption that there was scientific evidence that ruthenium was inoperative, i.e., that it would not catalyze the hydrogenation process of the patent. By "scientific evidence" I mean "reliable" or "conclusive" scientific evidence as explained in Paragraph 7 herein. I do not regard failure to obtain the desired result in several exploratory experiments as conclusive scientific evidence of inoperability. I recognized during prosecution of the Blackwood et al application and I recognize now that particular research experiments falling within the scope of a claimed invention may be unsuccessful without that invention being inoperative and the claims invalid. I also recognized during prosecution, and I recognize now, that the failure of some experiments does not preclude inventors from properly claiming an invention that broadly encompasses such experiments because the reasons for failure may be apparent upon investigation. For example, investigation may reveal that the experiments were carried out by incompetent or inexperienced technicians or that the specific circumstances or conditions employed led to failure, e.g., use of a relatively inactive catalyst sample, inadequate time, or choice of particular reaction medium or conditions. Therefore, I would not regard such experiments as conclusive scientific evidence of inoperability, i.e., that the process cannot be successfully carried out without the exercise of more than ordinary skill in the art. Moreover, it was not then, and is not now, my understanding of patent law that, in the light of experimental failure, successful experiments had to be

conducted before claims encompassing the experimental failures could be filed.

9. The statements in Paragraph 9 of my Supplemental Affidavit are based on the hypothetical assumption that the hydrogenation of 7-chloro-6-methylenetetracycline could not be carried out as taught by the application. The comments made in the preceding paragraph herein are also applicable to Paragraph 9 of my Supplemental Affidavit. In fact, said Paragraph 9 of my Supplemental Affidavit inadvertently overstates my speculation in referring to "any evidence" that Pfizer had been unable to successfully carry out the hydrogenation of a 7-chloro-6-methylenetetracycline. The "evidence" referred to should be "reliable" or "conclusive" scientific evidence as explained in Paragraph 7 herein. The fact is that I was not interested in any and every unsuccessful experiment carried out by Pfizer's research scientists. I recognized then and recognize now that a variety of factors may render a particular experiment unsuccessful. However, such experiments do not demonstrate that the process sought to be performed is inoperative. I would have been interested, therefore, only in conclusive scientific evidence that showed that the hydrogenation could not be conducted. Moreover, with respect to both Paragraphs 8 and 9 of this Affidavit I believe it proper to make of record my understanding that there is no legal obligation upon inventors or assignees to call the attention of the Patent Office to experimental failures as long as they have reasonable basis to believe the invention as claimed is operable and can be practiced through the use of ordinary knowledge and skill in the art.

10. With regard to Paragraph 10 of my Supplemental Affidavit, I used the term "scientific evidence" in accordance with the meaning I explained above in Paragraph 8 herein. It was known to me during the prosecution of the Blackwood et al application that antibiotics exhibit differences between *in vitro* and *in vivo* activity against the same microorganisms, and I so advised Mr. Cohen and Mr. Gross. For example, it was well known to me that an antibiotic compound displaying substantial activity *in vitro* against a particular microorganism is not necessarily active *in vivo* against the same organism. It was likewise known to me that both *in vivo* and *in vitro* antibacterial test results reflect the "actual" activity of the compound, *in vitro* testing reflecting activity in topical applications and *in vivo* testing reflecting activity in systemic applications. I note that both topical and systemic applications are taught in the Blackwood et al disclosure. When I passed the doxycycline patent to issue I did not assume that doxycycline is active *in vivo* against each and every microorganism against which it displays *in vitro* activity, and such considerations did not enter into my decision to allow the claims. My only reliance on the affidavits was to establish utility. The comparisons given in the affidavits were otherwise immaterial to me; what was material was that doxycycline was useful. When I passed the case to issue I was fully satisfied that the compounds claimed were patentable in that they were different from the prior known 6-deoxytetracyclines, they were useful and, since a unique process was necessary to bring them to the public, they were not obvious within the meaning of 35 U.S.C. 103.

11. I was the Examiner to whom application Serial No. 31,236 of May 23, 1960 was assigned. On September 16, 1960 I issued a rejection of claims in that application and stated that

> the exact structure of the compounds is not known and that the suggested structure may be in error.

I based that rejection in part on a passage in the application stating

> For convenience, these compounds are hereinafter referred to as 6-methylene-11a-halotetracyclines. It is to be understood that the proposed structure has not been proven to total synthesis and may subsequently be found in error.

I issued that rejection because the quoted disclosure passage appeared to raise a doubt with respect to the accuracy of the claim definition of the invention. I subsequently withdrew the rejection upon receipt of a response which pointed out that the disclosure did not establish that the structure specified in the claims was in error, but merely indicated that applicants' belief with respect to the disclosure could later be found to be in error on the basis of total synthesis. The response also informed me of the basis on which applicants formed their belief of the structural assignments made in the disclosure and candidly conceded that the structure had not been unequivocally established.

This issue was not present in the doxycycline application, whose disclosure and claims unequivocally defined the products of the invention as 6-epi-6-deoxytetracyclines

> since the steric configuration of the 6-methyl group is opposite to that of the known 6-deoxytetracyclines. (File wrapper, p. 1)

This defined the new compounds by reference to the closest prior known compounds, and, in my opinion, fully met statutory requirements, regardless of the state of knowledge of tetracycline stereochemistry in 1961. Since an adequate definition of the invention was available, it constituted the appropriate and correct mode of claiming. Under the circumstances, product-by-process claims were definitely unnecessary.

As I stated in my Affidavit of October 9, 1974, I understood the term "6-epi" as used in the Pfizer application to indicate a reversal of the substituents at the 6-position with reference to the known 6-deoxy compounds. The confusion I referred to in Paragraph 11 of my Supplemental Affidavit was created by the fact that a publication which Mr. Oglesby brought to my attention (Muxfeldt, Angew. Chemie, Vol. 1, pp 372-381, 1962) applied "epi" nomenclature to the prior known 6-deoxytetracyclines. In order to avoid conflicting terminology I therefore proposed substitution of alternative nomenclature, as recorded at pp 101-102 of the file wrapper, and Mr. Oglesby complied with my request.

12. With regard to Paragraph 12 of my Supplemental Affidavit, I acknowledge that the statement in my January 19, 1965 Action reading:

> Thus the claimed compounds have a methyl group in the 6-position which allegedly is oriented in a different manner than the corresponding compounds produced by fermentation methods. (file wrapper, p 93)

is clearly in error, as I recognize from a review of that portion of the file wrapper which preceded it. I do not know what caused me to make this erroneous

statement. However, Paragraph 12 of my Supplemental Affidavit records a current explanation of an error occurring in a relatively few words written over 10 years ago and at this point in time it is difficult for me to maintain a clear line of demarcation between explanation, reconstruction, and recollection regarding the specific facts and circumstances surrounding my preparation of the January 19, 1965 Action. In fact, upon reconsideration I do not recall that my above quoted erroneous statement was based upon the April 26, 1962 amendment, and I regret that the statement in Paragraph 12 of my Supplemental Affidavit states that this amendment was the basis for my erroneous statement. My erroneous statement may have been the result of the April 26, 1962 amendment, a typographical error, negligence, or some inadvertent error in the preparation of my handwritten draft of the Action. When I first reviewed the patent file at the request of the defendants' counsel preliminary to a day-long conference in the Fall of 1973 with five or six attorneys representing the defendants herein at the Kenyon & Kenyon New York office, the above quoted statement struck me immediately as an obvious error, and ever since I have been consciously trying to find an explanation for this inexcusable error. It is clear from the file wrapper that the 6-methyl group of the claimed compounds is oriented in the same way as in the compounds produced by fermentation.

The speculation on which Paragraph 12 of my Supplemental Affidavit is founded totally overlooks Mr. Oglesby's April 30, 1963 amendment (file wrapper pp 69-74, especially pp 70-71) and the Muxfeldt publication attached thereto (file wrapper, pp 79-88). The November 9, 1964 amendment which was made at

my suggestion makes it clear that I was aware of and read that April 30, 1963 amendment in October or November of 1964, and that I particularly read the portions of the amendment referring to Muxfeldt and at least portions of the Muxfeldt publication attached thereto. Those portions of the file wrapper make it very clear that inversion of the 6-methyl group occurs in hydrogenating the fermentation products to make the known 6-deoxy compounds, and thus that the orientation of the 6-methyl group in the newly claimed compounds is the same as in the fermentation products. It is because of this clarity of the file wrapper that it is difficult for me to account for the erroneous statement which appears in my January 19, 1965 Action.

In addition, I note that in his March 5, 1965 response Mr. Oglesby corrected that error, and before I passed the application to issue I undoubtedly read and appreciated that correction, reading as follows:

> This rejection states that 'the claimed compounds have a methyl group in the 6-position which allegedly is oriented in a different manner than the corresponding compounds produced by fermentation methods.' Actually, the second full paragraph of page 1 of applicants' original disclosure makes it unequivocally clear that the claimed compounds have a methyl group in the 6-position which is oriented in the opposite direction to that of the known 6-deoxytetracyclines produced by hydrogenation of fermentation produced tetracyclines. In this connection, it will be recalled that the prior art catalytic hydrogenation of fermentation produced tetracyclines not only replaces the 6-OH substituent with a hydrogen substituent but also

> reverses the spatial orientation of the 6-methyl substituent, the orientation of the hydrogen substituent being opposite thereto in the final product.

The statements in Paragraph 12 of my Supplemental Affidavit are not intended to imply that the superiority of doxycycline to the previously known 6-deoxy-5-oxytetracycline was predictable. I had no information during prosecution of the Blackwood et al application and have none now which would allow me to predict the relative degree of activity, if any, of epimer pairs. I recognize that doxycycline and the previously known 6-deoxy-5-oxytetracycline are both synthetic products and I know of no way to predict *a priori* which will be the more active. This unpredictability is also true insofar as I know, with respect to fermentation products and their epimers. Thus, it was immaterial to patentability, from my viewpoint, that the 6-methyl group has the same orientation in doxycycline as in oxytetracycline.

13. With reference to Paragraph 13 of my Supplemental Affidavit, the file wrapper makes it abundantly clear to me that Mr. Nicholas E. Oglesby made no misrepresentations with respect to the orientation of the 6-methyl group in the new 6-epi compounds, in the known 6-deoxy compounds or in the fermentation products. Indeed, page 1 of the specification of the Blackwood et al application (file wrapper, p 1) makes it clear that the 6-epi compounds (e.g., doxycycline) differ from the known 6-deoxy compounds only in that the steric configuration of the 6-methyl group in the 6-epi compounds is opposite to that of the known 6-deoxy compounds. Knowledge of this difference, coupled with the fact that the prior art did not disclose a process for preparing the claimed 6-

epi compounds, made immaterial to me whether the steric configuration of the 6-methyl group in the 6-epi compounds was the same as, or different from, the orientation of that group in the fermentation products.

Dated February 24, 1975

/s/ James Walter Adams, Jr.
James Walter Adams, Jr.

State of Ohio, County of Cuyahoga—ss:

Sworn to and subscribed before me this 24th day of February, 1975.

/s/ James H. Tilberry
Notary Public

JAMES H. TILBERRY, Attorney At Law
Notary Public—State of Ohio
My commission has no expiration date.
Section 147.03 R.C.

Oglesby—March 18, 1975.

Affidavit of Nicholas E. Oglesby, Jr.

United States District Court, District of Minnesota.

In re: Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions, 4-71 Civ. 435 and the following action:

Pfizer Inc., Plaintiff, -against- International Rectifier Corporation, Rachelle Laboratories Italia, S.p.A., Rachelle Laboratories, Inc., Rachelle Pharmaceuticals International, S.A., and USV Pharmaceutical Corporation, Defendants. 4-73 Civ. 188.

State of Delaware, County of New Castle—ss.

Nicholas E. Oglesby, Jr., being duly sworn, deposes and says the following:

(1) I am the Nicholas E. Oglesby, Jr., who prepared and prosecuted the Pfizer application which issued as U. S. Patent 3,200,149 covering doxycycline and other new products and process for making the same.

(2) As of May 5, 1961, I did not know the stereochemical formulas of the claimed compounds of application Serial No. 106,146 filed May 5, 1961 (hereinafter "the application"), which resulted in U. S. Patent 3,200,149.

(3) I did not omit stereochemical formulas in the application with an intent to deceive any Examiner.

(4) As of May 5, 1961, I did not believe that the absolute stereochemical configuration of the known 6-deoxy compounds or of the new 6-epi-6-deoxy compounds was relevant to the patentability of doxycycline.

(5) It has been my consistent understanding since before the filing of the application that there has been

no doubt that the actual orientation of the 5-hydroxyl group in doxycycline is identical with the orientation of that group in oxytetracycline and in the previously known 6-deoxy-5-oxytetracycline produced by hydrogenolysis of oxytetracycline.

(6) As of May 5, 1961, I was advised by Pfizer and believed Pfizer believed, based on the scientific evidence available to it, that the diagrams in Belgian Patent 572,584 which purport to describe the configurations of the products produced by the process described in said patent were incorrect at the 5 and 6 positions.

(7) As of May 5, 1961, I was advised by Pfizer and believed that Pfizer believed that those stereochemical diagrams in Belgian Patent 572, 584 which purport to describe the configurations of the products produced by the process described in the patent were in error.

(8) As of May 5, 1961, I was advised by Pfizer and believed that Pfizer believed that Belgian Patent 572,584 did not depict doxycycline.

(9) As of May 5, 1961, I believed and had previously rendered an opinion that Drs. Blackwood, Beereboom, Rennhard and Stephens were the first and joint inventors of the subject matter claimed in the application.

(10) As of May 5, 1961, based on information that I had obtained from Pfizer, I believed that Belgian Patent 572,584 did not describe either the process or products claimed by Pfizer in the application as filed.

(11) As of May 5, 1961, I believed that I had no obligation to bring Belgian Patent 572,584 to the Examiner's attention at the time I filed the application.

(12) On or about March 29, 1962, at a personal interview, I brought Belgian Patent 572,584 to Examiner Adams' attention.

(13) On or about March 29, 1962, I informed Examiner Adams, at a personal interview, that Pfizer believed the diagram in Belgian Patent 572,584 was incorrect at the 5-position with respect to the orientation of the hydroxyl group.

(14) On or about March 29, 1962, I informed Examiner Adams, at a personal interview, that Pfizer believed the diagram in Belgian Patent 572,584 was incorrect at the 6-position, i.e., that it did not correctly depict the 6-position stereochemistry of the product actually produced by the process of the Belgian Patent.

(15) On or about March 6, 1963, at a personal interview, I informed Examiner Berg that while Pfizer had previously believed that the 5-hydroxyl group in the compounds claimed by Pfizer differed from the orientation shown in the Belgian Patent, doubt with respect to the accuracy of this belief had now been raised by Muxfeldt, Angew. Chem., Vol. 1, pp. 373-381 (1962).

(16) I believe that the file wrapper of the application demonstrates to one skilled in the art that the orientation of the 5-OH in doxycycline was uncertain in 1962.

(17) Beginning on or about April 24, 1963, I believed that *In re LeGrice*, 133 USPQ 365 (May 4, 1962), rendered moot the issue of possible Von Bramer anticipation by Belgian Patent 572,584.

(18) When I added the claim for 6-epi-6-deoxytetracycline to the application by the amendment filed on or about April 30, 1963, I was willing to assume

that compound was depicted by the Belgian Patent but was of the opinion that this was of no legal significance because of *In re LeGrice*.

(19) On or about April 14, 1964, I contacted Examiner Modance by telephone and advised him, *inter alia,* of the expected meeting with Woodward which would shed more conclusive light on the structure of the compounds under discussion. Subsequently and on or about July 9, 1964, I advised Mr. Modance at a personal interview that the orientation of the 5-position hydroxy substituent was up in the air by virtue of a proposal of a member of Pfizer's Research Group, that Dr. Woodward was inclined not to agree with that proposal, that work was being done to resolve the matter, we did not know when the same would be resolved but that in any event the issue was moot because *In re LeGrice,* as well as the more recently decided *In re Brown,* 141 USPQ 245 (April 9, 1964), decision.

(20) On or about July 9, 1964, I again advised Examiner Modance that Pfizer was uncertain about the orientation of the 5-hydroxy substituent in doxycycline.

(21) I made no effort to advance the prosecution of the application by arguing the merits thereof from the time of filing the amendment of April 30, 1963 until after April 9, 1964.

(22) Although there had previously been no doubt in my mind but that *In re LeGrice* rendered moot the issue of possible Von Bramer anticipation by Belgian Patent 572,584, *In re Brown* substantiated my conviction.

(23) I did not withhold any information known to me from any Examiner with the intent of misleading

him nor did I withhold information that I believed might be of interest to him.

(24) As of May 5, 1961, I believed that the application as filed described the prior art most pertinent to the claimed subject matter.

(25) I did not intentionally misrepresent any facts to this Court.

(26) I believe that Pfizer did not need to know the absolute stereochemical configuration of doxycycline in order to file the application as filed.

(27) I believe that Pfizer did not need to know or to identify the absolute stereochemical configuration of doxycycline in order to be entitled to a patent on doxycycline as claimed.

(28) During the pendency of the application, I believe that the Examiner understood that the absolute stereochemical configuration of doxycycline was unknown.

(29) I did not delete any matter from any draft of the application with the intent of misleading any Examiner.

(30) I do not believe that Pfizer needed to know the stereochemical configuration of doxycycline relative to oxytetracycline in order to file the application as filed.

(31) I do not believe that Pfizer needed to know or to identify the stereochemical configuration of doxycycline relative to oxytetracycline in order to be entitled to a patent on doxycycline as claimed.

(32) By the use of the prefix "6-epi" in the application, I intended to indicate that the new compounds had the opposite steric configuration at the 6-position from the products produced by the hydrogenation of

the corresponding fermentation products, i.e., the known 6-deoxytetracyclines.

(33) I believed throughout the prosecution of the application that the Examiners understood that the prefix "6-epi" as used in the application meant that the substituents at the 6-position had the opposite configuration from the products produced by hydrogenation of the corresponding fermentation products, i.e., known 6-deoxytetracyclines.

(34) I do not believe any Examiner was interested in knowing the absolute stereochemical configuration of doxycycline.

(35) I did not withhold any information from the disclosure of the application with the intention of misleading any Examiner.

(36) I do not believe the absolute stereochemical configuration of doxycycline was relevant to the patentability of doxycycline.

(37) I do not believe the structure issue raised in SN. 31,236 was present in or relevant to the doxycycline application.

(38) I believed throughout the prosecution of the application, that the amendments fully complied with the Patent Office rules and prevailing practice.

(39) I did not represent to any Examiner that the 6-CH_3 in doxycycline was oriented in the opposite direction from the orientation of the 6-CH_3 in fermentation produced tetracyclines.

(40) I did not state to any Examiner that doxycycline was an epimer of a natural fermentation produced tetracycline.

(41) The term "epi" has never had a meaning to me which connotes a relationship to natural fermentation produced compounds.

(42) My arguments in the 1962 and 1965 amendments to the application drew no analogy to fermentation produced compounds but, instead, they countered the Examiner's supposition that the 6-epimers were routine developments in the art.

(43) I fully advised the Examiners as to the "up" and "down" positions of the 6-CH_3 in the fermentation produced compounds, the known 6-deoxytetracyclines, and in doxycycline.

(44) I believe the file wrapper teaches one skilled in the art that the 6-CH_3 in doxycycline is oriented in the same direction as 6-CH_3 in fermentation produced tetracyclines.

(45) I did state to the Examiners that doxycycline was the 6-epimer of the previously known 6-deoxy-5-oxytetracycline (McCormick compound).

(46) I did state to the Examiners that the previously known 6-deoxy-5-oxytetracycline was produced synthetically (not by fermentation).

(47) I used the term "normal" at page 66 of the file wrapper of the application to refer to the first discovered member of the epimer pair, i.e., the known 6-deoxy-5-oxytetracycline.

(48) By the use of the word "normal" at page 66 of the file wrapper, I did not imply that the first discovered or known 6-deoxy-5-oxytetracycline had a "natural" configuration at the 6-position (viz., the same configuration at the 6-position as the parent tetracycline antibiotic produced by fermentation).

(49) I believe that it was immaterial to the patentability of doxycycline that 6-CH_3 has the same orientation in doxycycline as in Terramycin.

(50) I did not take any action in the Patent Office with the intention of misleading or confusing Examiner Adams into making the error which appears at page 93 of the file wrapper.

(51) I did not make any statements to any Examiner with the intent of misleading him.

(52) I made a good faith attempt in my March 1965 amendment to correct the error made by Examiner Adams at page 93 of the file wrapper of the application.

(53) I did not represent to any Examiner that doxycycline was effective *in vivo* as to every microorganism against which it was effective *in vitro*.

(54) I was unaware of the 1964 Dr. English report during the prosecution of the application.

(55) I did not withhold any comparative data known to me to be pertinent to *in vivo* or *in vitro* activity.

(56) During prosecution of the application, I requested Pfizer to conduct an investigation of possible coproduction of doxycycline in the hydrogenolysis of Terramycin and I believe that the results of this investigation failed to establish coproduction.

(57) I told Examiners Modance and Adams that Pfizer's 1958 observation of possible coproduction was based on a product produced by the hydrogenolysis of Terramycin and that its later investigation was conducted on what was considered by Pfizer to be an "equivalent product".

(58) I did not tell any Examiner that the "equivalent product" on which Pfizer conducted its investigation of possible coproduction was produced by following a specific example in the prior art.

(59) I believe the information reported by me to the Examiner at pages 105-107 of the file wrapper faithfully represented the results of Pfizer's laboratory work.

(60) I informed Examiners Modance and Adams that prior Pfizer applications contained speculation that doxycycline might be coproduced in the hydrogenolysis of Terramycin.

(61) I did not and do not now believe that the prior Pfizer applications were prior art to the doxycycline application.

(62) I told the Examiner that "it cannot be stated unequivocally that the entity is not α-6-deoxy-5-oxytetracycline", i.e., doxycycline.

(63) I was advised by Examiners Modance and Adams that the Examiner could not reject doxycycline on the ground of coproduction unless the prior art indicated the coproduction of doxycycline.

(64) I informed the Examiner at page 106 of the file wrapper that Pfizer had paper chromatographic evidence of possible coproduction of doxycycline.

(65) I was advised at the conclusion of Dr. Murai's work in June 1964 that although it could not be stated unequivocally that the active entity is not doxycycline, Pfizer did not think that it was doxycycline.

(66) I offered to make all information concerning possible coproduction available to Examiners Modance and Adams.

(67) I was advised by Examiners Modance and Adams and believed that they were not interested in, and did not consider material, any evidence of possible coproduction which Pfizer had.

(68) I did not conceal any evidence known to me of possible coproduction from any Examiner with the intent to deceive him.

(69) During prosecution of the application, I believed ruthenium was operative in the process disclosed in the application.

(70) During prosecution of the application, I believed 7-chloro-6-epi-6-deoxy-5-oxytetracycline could be made by the process disclosed in the application.

(71) During prosecution of the application, I do not believe I was aware of any experiment concerning ruthenium or 7-chloro-6-epi-6-deoxy-5-oxytetracycline which had failed to produce the desired results.

(72) With reference to the July 9, 1964 interview with Examiner Modance, I testified in response to questions at my deposition on March 5, 1974 as follows:

"Q Can you recall what you discussed, or the substance of what you discussed, with Mr. Modance?

"A I can.

"Q Would you please relate that.

"MR. EDGAR MARTIN: Go ahead.

"A I identified the Stephens and Conover application. I believe I had it at hand at the time, or my copy of it, pointed to the Example 1 from which the quotation which appears at the bottom of page 106 of the file wrapper was taken, and told him that that quotation had necessitated

a substantial amount of laboratory work in behalf of Pfizer. I presented him with the notebooks, including the record of that work, showing the conclusion which is quoted at page 107 of the file wrapper and contents, in the first paragraph, and offered to bring any other—to bring the people who had done the work to Washington, as well as any other knowledgeable Pfizer employee, and even to undertake any other work that he believed necessary in order to resolve the possibility of coproduction.

"Mr. Modance advised me that the Patent Office had no right to inquire into coproduction unless it was suggested by the prior art, and pointed out that, therefore, he was not interested in this work or pursuing the discussion any further in connection with it.

"And I offered to make a record, as I did in connection with the interview, subsequent interview, with Mr. Adams, the entire story.

"He specifically requested that I do not—that I did not do that. And so I did not. Bearing in mind that there was not an issue of record insofar as the Patent Office was concerned, and I was, therefore, not under any burden to bring those remarks into the record.

"Q Did you prepare a memorandum of this meeting with Mr. Modance?

"A I believe that I did, but I'm not certain. It was the type of thing that probably would have been the subject matter of a memorandum or other communication, because it, to me, at the time, had direct bearing on the tetracycline

litigation. That is, Mr. Modance's comments with respect to not being interested in coproduction unless it were suggested by the prior art."

I believe that testimony to be true.

(73) With reference to my understanding of the term "epi" during prosecution of the application, I testified in response to a question at my deposition on March 6, 1974 as follows:

"It was or had a significance meaning the same as what preceded, except for the designated Position 6 in this case, or 4 in connection with the compounds you were discussing."

* * *

"A Mr. Heller, I have been sitting here cogitating opposite the table from you during our recent break, thinking about your question. It bothers me for at least two reasons. In the first place, you seem to be driving, for reasons I am not certain of, the terminology 'epi' in the direction of a fermentation produced source.

"I gave you earlier in this line of questioning my understanding of the meaning of 'epi' and it was not related to fermentation orientation.

"Additionally, if it so happens that the predecessors of the epitetracyclines that were known prior to the filing date of the subject—of the application of the patent in suit were fermentation produced, this had no bearing on my use of the term 'epi' in the application.

"Next, the term 'epi,' as used today, has, as I understand it, no relationship to fermentation sources.

"I can't go any further in this area, I don't believe."

I believe that testimony to be true.

(74) With reference to application Serial No. 841,928 of September 24, 1959 (USV Exhibit No. 58) and my July 9, 1964 interview with Mr. Modance, I testified in response to a question at my deposition on March 5, 1974 as follows:

"A That is exactly what I wanted to verify.

"The quotation at page 106 of the contents of the file wrapper of the patent in suit is, as you have correctly directed my attention, Mr. Heller, taken from the earlier Stephens application, USV Exhibit 56.

"Nevertheless, I can specifically recall that the C application, so-called—that is, the application of USV number exhibit—USV Exhibit No. 58, was presented to Mr. Modance.

"I may also have presented USV Exhibit No. 56, but I do not recall."

I believe that testimony to be true.

(75) With reference to abandoning application Serial No. 841,928 of September 24, 1959 (USV Exhibit No. 58) "subject to Patent Office approval" as discussed with Examiner Modance at the July 9, 1964 interview, I testified in response to a question at my deposition on March 5, 1974 as follows:

"Q What do you mean by 'subject to Patent Office approval'?

"A I mean that—I mean, by that, that the work underlying whether or not there had been coproduction was brought to Mr. Modance's atten-

tion; and, at the same time, that he was advised that if he felt that there was any reason to maintain the pendency of the application represented by USV Exhibit 58, we would do so.

"He advised that, as far as he was concerned, we were at liberty to abandon it, it was of no interest to him since the Patent Office could not and would not rely on coproduction unless it was suggested by the prior art."

I believe that testimony to be true.

(76) With reference to the February 23, 1965 interview with Examiner Adams, I testified in response to questions at my deposition on March 5, 1974 as follows:

"Q Subsequent to the interview we have just discussed, with Mr. Modance, did you discuss USV Exhibits 58 and/or 56 with Mr. Adams?

"A Yes. There is a record, a complete record, of such discussion, pages 106 through 107 of the contents of the file wrapper of the application for the patent in suit."

* * *

"Q Did you discuss with Mr. Adams the quotation which appears at the penultimate line of the file wrapper page 106?

"A Yes, I did.

"Q Did you advise him that that quotation had come from the patent application?

"A Yes.

"You will note there is a sentence at page 106, just preceding the last paragraph, in which the examiner agreed that it would be quite proper if applicants desire to include a brief statement

of the conclusions reached as the result of the investigation—such investigation.

"Mr. Adams and I discussed this entire situation in quite detail. He was very interested in it.

"After it was concluded, he was of a mind similar to Mr. Modance, in that it really was not of concern to the record.

"I was of a different opinion, because the whole situation had been triggered as a result of a statement by Mr. Adams in the official action that I was responding to in the amendment which begins at page 98; and, therefore, I did wish to make a statement in the record, in the event that if, at some subsequent date, someone questioned the meaning or significance of Mr. Adams' remark in his official action, that we would have a recorded explanation."

I believe that testimony to be true.

Further deponent saith not.

/s/ N. E. Oglesby, Jr.
Nicholas E. Oglesby, Jr.

Sworn to and subscribed before me this 18th day of March, 1975.

/s/ Gertrude M. Mullen
Notary Public

NEO/cas